



BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 331

9 CFR Part 121

[Docket No. APHIS-2009-0070]

RIN 0579-AD09

Agricultural Bioterrorism Protection Act of 2002; Biennial Review and Republication of the Select Agent and Toxin List; Amendments to the Select Agent and Toxin Regulations; Technical Amendment

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule; technical amendment.

SUMMARY: As part of a final rule published in the *Federal Register* on October 5, 2012, we amended and republished the list of select agents and toxins that have the potential to pose a severe threat to animal or plant health, or to animal or plant products. In that final rule we removed bovine spongiform encephalopathy agent from the list of select agents or toxins, but we neglected to remove it from the list of those select agents or toxins whose seizure must be reported within 24 hours by telephone, facsimile, or e-mail. We are remedying that oversight in this document. We are also updating the name of another select agent to reflect its most current scientific classification, correcting a typographical error, and updating the name of a guidance document referenced in the regulations.

DATES: Effective [Insert date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Dr. Keith Wiggins, Acting National Director, Agriculture Select Agent Services, APHIS, 4700 River Road Unit 2, Riverdale, MD 20737-1231; (301) 851-2024.

#### SUPPLEMENTARY INFORMATION:

##### Background

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 provides for the regulation of certain biological agents that have the potential to pose a severe threat to both human and animal health, to animal health, to plant health, or to animal and plant products. The Animal and Plant Health Inspection Service (APHIS) has the primary responsibility for implementing the provisions of the Act within the U.S. Department of Agriculture. Veterinary Services (VS) select agents and toxins are those that have been determined to have the potential to pose a severe threat to animal health or animal products. Plant Protection and Quarantine (PPQ) select agents and toxins are those that have the potential to pose a severe threat to plant health or plant products. Overlap select agents and toxins are those that have been determined to pose a severe threat to both human and animal health or animal products. Overlap select agents are subject to regulation by both APHIS and the Centers for Disease Control and Prevention, which has the primary responsibility for implementing the provisions of the Act for the Department of Health and Human Services.

On October 5, 2012, we published in the *Federal Register* (77 FR 61056-61081, Docket No. APHIS-2009-0070) a final rule<sup>1</sup> that amended and republished the list of select agents and toxins that have the potential to pose a severe threat to animal or plant health, or to animal or plant products; and amended the regulations in order to add definitions and clarify language concerning security, training, biosafety, biocontainment, and incident response.

In that rule, we removed bovine spongiform encephalopathy agent from the list of VS select agents and toxins set out in 9 CFR 121.3(b). However, paragraph (f)(3)(i) of that section continues to list bovine spongiform encephalopathy agent among those VS select agents and toxins whose seizure by any Federal law enforcement agency must be reported within 24 hours by telephone, facsimile, or e-mail. We are removing this outdated reference. Additionally, in paragraph (d)(9) of that section we reference pigeon paramyxovirus-1, but the numerical suffix appears as “-12” instead of “-1.” We are correcting that.

The list of PPQ select agents and toxins is set out in 7 CFR 331.3(b) and includes the fungal plant pathogen, *Phoma glycinicola* (formerly *Pyrenochaeta glycines*). Recent molecular and phylogenetic studies have resulted in the reclassification of this pathogen as *Coniothyrium glycines*.<sup>2</sup> We are updating the regulations accordingly.

---

<sup>1</sup> To view the final rule, its preceding proposed rule, and the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2009-0070>.

<sup>2</sup> de Gruyter J, Woudenberg JHC, Aveskamp MM, et al. (2013). Redisposition of phoma-like anamorphs in *Pleosporales* re-evaluation. *Studies in Mycology* 75: 1–36. <https://www.sciencedirect.com/science/article/pii/S0166061614600014?via%3Dihub>.

The regulations in 7 CFR 331.11 and 9 CFR 121.11 require development of a security plan that provides for measures sufficient to safeguard the select agent or toxin against unauthorized access, theft, loss, or release. In paragraph (g) of those sections, we recommend that an individual or entity consider the document entitled, “Security Guidance for Select Agent or Toxin Facilities” when developing the required plan.

We are correcting the name of that document, which has been shortened to “Security Plan Guidance,” in its most recent update.

#### List of Subjects

##### 7 CFR Part 331

Agricultural research, Laboratories, Plant diseases and pests, Reporting and recordkeeping requirements.

##### 9 CFR Part 121

Agricultural research, Animal diseases, Laboratories, Medical research, Reporting and recordkeeping requirements.

Accordingly, 7 CFR part 331 and 9 CFR part 121 are amended as follows:

#### Title 7—Agriculture

##### PART 331—POSSESSION, USE, AND TRANSFER OF SELECT AGENTS AND TOXINS

1. The authority citation for part 331 continues to read as follows:

Authority: 7 U.S.C. 8401; 7 CFR 2.22, 2.80, and 371.3.

##### § 331.3 [Amended]

2. In § 331.3, paragraph (b) is amended by removing the entry “*Phoma glycinicola* (formerly *Pyrenochaeta glycines*);” and adding, in alphabetical order, an entry for “*Coniothyrium glycines*, (formerly *Phoma glycinicola*, *Pyrenochaeta glycines*);”.

§ 331.11 [Amended]

3. In § 331.11, paragraph (g) is amended by removing the words “Security Guidance for Select Agent or Toxin Facilities” and adding the words “Security Plan Guidance” in their place.

Title 9—Animals and Animal Products

PART 121—POSSESSION, USE, AND TRANSFER OF SELECT AGENTS AND TOXINS

3. The authority citation for part 121 continues to read as follows:

Authority: 7 U.S.C. 8401; 7 CFR 2.22, 2.80, and 371.4.

§ 121.3 [Amended]

4. Section 121.3 is amended as follows:

a. In paragraph (d)(9), by removing “-12” and adding “-1” in their place; and

b. In paragraph (f)(3)(i), by removing the words “bovine spongiform encephalopathy agent,”.

§ 121.11 [Amended]

5. In § 121.11, paragraph (g) is amended by removing the words “Security Guidance for Select Agent or Toxin Facilities” and adding the words “Security Plan Guidance” in their place.

Done in Washington, DC, this 19<sup>th</sup> day of September 2018.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2018-20694 Filed: 9/21/2018 8:45 am; Publication Date: 9/24/2018]